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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,242

06/24/2003

Ye Fang

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CORNING INCORPORATED

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CORNING, NY 14831

EXAMINER

YANG, NELSON C

ART UNIT

PAPER NUMBER

1641

NOTIFICATION DATE

DELIVERY MODE

05/13/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/602,242	<b>Applicant(s)</b> FANG ET AL.	
	<b>Examiner</b> Nelson Yang	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-18,27,42-50,52-58,60-62,64 and 66 is/are pending in the application.
- 4a) Of the above claim(s) 3,6-8 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,10-18,42-50,52-58,60-62,64 and 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Response to Amendment***

1. Claims 1, 4-5, 10-18, 42-62, 64, 66 are currently pending.
2. Claims 3, 6-8, 27 are withdrawn.
3. Claims 9, 19-26, 28-41, 63, 65 are cancelled.

***Rejections Withdrawn***

4. Applicant's arguments on p. 9-10 and declaration of common ownership under 35 USC 103(c) is found persuasive, and therefore the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4-5, 10-18, 42-48, 51-54, 57-62, 64, 66 are rejected under 35 U.S.C. 103(a) as being obvious over Lahiri et al. [US 2002/0019015] in view of Löfås [US 5,922,594] in light of Hildreth [US 2002/0128227].

With respect to claims 1, 4, 5, Lahiri et al. teach an array comprising a plurality of probe biological membrane microspots associated with a surface of a substrate in an environment exposed to air under ambient or controlled humidities (abstract, para. 0006, 0094, 0105), wherein the surface is coated with a amine presenting molecule such as thioalkyl amine (para. 0016-

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0017). The biological membrane microspots comprise a probe that binds with a target compound (para. 0024, 0081), and further teach detection of a binding event with the membrane bound protein. Lahiri et al. further teach detection of a binding event using the probe array after incubation in a humid chamber at room temperature for a hour (para. 0094), which would also enable lateral distribution of the lipid molecules. Although Lahiri et al. do not specify the incubation would be to enable lateral fluidity of the lipids, applicants have not specified any other requirement to enable lateral fluidity of the lipids other than to incubate the array in a humid chamber, this limitation would read on the method of Lahiri et al. since Lahiri et al. also teach the step of incubating the array in a humid chamber. Lahiri et al., however, do not specify monitoring for binding activity of at least one of the biological lipid membranes with toxin in a sample

Löfås, however, teaches liposomes containing ganglioside  $G_{M1}$  for detecting cholera toxins in a sample (column 5, 6, example 1), wherein cholera is a bacterial toxin, as evidenced by Hildreth (see para. 0041). Löfås further teaches that this allows for the detection and determination of the specific activity of the lipid bilayer for binding to cholera toxins, thus providing important information of binding of cholera toxin with biological membranes (column 6, lines 1-28).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used gangliosides such as  $G_{M1}$  as probes in the array of Lahiri et al., as suggested by Löfås et al., in order to be able to detect the presence of cholera toxin in a sample utilizing a system similar to biological membranes, thus allowing for a more accurate assessment of the effects of the cholera toxin on biological membranes.

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7. With respect to claims 10, 11, 14, Lahiri et al. further teach that the analyte may be labeled and detected (para. 0023).
8. With respect to claim 12, Lahiri et al. teach detecting a physical change in physical properties at the interface due to a binding event between the target and the probe (para. 0081).
9. With respect to claim 13, Lahiri et al. teach unlabeled target (para. 0024, 0081).
10. With respect to claim 15, Lahiri et al. teach synthetic or natural analytes (para. 0068), as discussed above.
11. With respect to claims 16, 18, Lahiri et al. teach glass slides (para. 0052-0055).
12. With respect to claim 17, Lahiri et al. teach nano-porous substrates (para. 0053).
13. With respect to claims 42, Lahiri et al. teach an array comprising a plurality of probe biological membrane microspots associated with a surface of a substrate in an environment exposed to air under ambient or controlled humidities (abstract, para. 0006, 0094, 0105), wherein the surface is coated with a amine presenting molecule such as thioalkyl amine (para. 0016-0017). The biological membrane microspots comprise a probe that binds with a target compound (para. 0024, 0081), and further teach detection of a binding event with the membrane bound protein. The biological membrane microspots comprise probes such as G-protein coupled receptors or G-proteins (para. 0021), which would bind to chemical toxins. Lahiri et al. further teach detection of a binding event using the probe array after incubation in a humid chamber at room temperature for an hour (para. 0094), which would enable lateral distribution of the lipid molecules. Lahiri et al., however, do not clearly disclose that the probes may include a bacterial toxin-binding receptor.

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Löfås, however, teaches liposomes containing ganglioside  $G_{M1}$  for detecting cholera toxins in a sample (column 5, 6, example 1), wherein cholera is a bacterial toxin, as evidenced by Hildreth (see para. 0041). Löfås further teaches that this allows for the detection and determination of the specific activity of the lipid bilayer for binding to cholera toxins, thus providing important information of binding of cholera toxin with biological membranes (column 6, lines 1-28).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used gangliosides such as  $G_{M1}$  as probes in the array of Lahiri et al., as suggested by Löfås et al., in order to be able to detect the presence of cholera toxin in a sample utilizing a system similar to biological membranes, thus allowing for a more accurate assessment of the effects of the cholera toxin on biological membranes.

14. With respect to claims 43-44, Lahiri et al. further teach that the analyte may be labeled and detected by fluorescence (para. 0023).

15. With respect to claim 45, Lahiri et al. teach washing to remove unbound targets (para. 0082).

16. With respect to claim 46, Lahiri et al. teach that the array of microspots is incubated with labeled cognate target and an unlabeled target compound, and the binding event between the unlabeled target compound and the probe is determined by measuring a decrease in the signal of the label due to competition between the cognate labeled target and the unlabeled target compound for the probe (para. 0024).

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17. With respect to claim 47, Lahiri et al. teach detecting a physical change in physical properties at the interface due to a binding event between the target and the probe (para. 0024, 0081), wherein the target is unlabeled (para. 0024, 0081).
18. With respect to claim 48, Lahiri et al. teach measuring a change in refractive index (para. 0081).
19. With respect to claim 51, as discussed above, the amines used by Lahiri et al. may be  $\gamma$ -aminopropylsilane (para. 0010).
20. With respect to claims 52, as discussed above, the amines used by Lahiri et al. may be polyethyleneimine (para. 0054).
21. With respect to claim 53, Lahiri et al. teach coating with  $\gamma$ -aminopropylsilane (para. 0010).
22. With respect to claim 54, the amines used by Lahiri et al. may be polyethyleneimine (para. 0054).
23. With respect to claims 57, 62, Lahiri et al. teach an array comprising a plurality of biological membrane microspots associated with a surface of a substrate in an environment exposed to air under ambient or controlled humidities (abstract, para. 0006-0009), wherein the surface is coated with a amine presenting molecule such as thioalkyl amine (para. 0011-0013). The biological membrane microspots comprise probes that bind to specific target analytes (para. 0009, 0031-0033). Lahiri et al. further teach detection of a binding event using the probe array after incubation in a humid chamber at room temperature for a hour (para. 0094), which would enable lateral distribution of the lipid molecules. Lahiri et al., however, do not specify

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monitoring for binding activity of at least one of the biological lipid membranes with toxin in a sample.

Löfås, however, teaches liposomes containing ganglioside  $G_{M1}$  for detecting cholera toxins in a sample (column 5, 6, example 1), wherein cholera is a bacterial toxin, as evidenced by Hildreth (see para. 0041). Löfås further teaches that this allows for the detection and determination of the specific activity of the lipid bilayer for binding to cholera toxins, thus providing important information of binding of cholera toxin with biological membranes (column 6, lines 1-28).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used gangliosides such as  $G_{M1}$  as probes in the array of Lahiri et al., as suggested by Löfås et al., in order to be able to detect the presence of cholera toxin in a sample utilizing a system similar to biological membranes, thus allowing for a more accurate assessment of the effects of the cholera toxin on biological membranes.

24. With respect to claims 58-61 as discussed above, the amines used by Lahiri et al. may be  $\gamma$ -aminopropylsilane (para. 0010).

25. With respect to claim 64, Löfås teach the detection of cholera toxin, which is a bacterial toxin, by binding to ganglioside  $G_{M1}$ .

26. With respect to claim 66, Lahiri et al. teach lipids printed on GAPS substrate (para. 0029), and would therefore have a mobile fraction of about 0.5, based on applicants own admission (see specification, para. 0041).



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27. Claims 49-50, 55, 56 are rejected under 35 U.S.C. 103(a) as being obvious over Lahiri et al. [US 2002/0019015] in view of Löfås [US 5,922,594] and in view of Cass [US 2002/0168692] in light of Hildreth [US 2002/0128227].

With respect to claims 49, Lahiri et al. teach an array comprising a plurality of probe biological membrane microspots associated with a surface of a substrate in an environment exposed to air under ambient or controlled humidities (abstract, para. 0006, 0094, 0105), wherein the surface is coated with a amine presenting molecule such as thioalkyl amine (para. 0016-0017). The biological membrane microspots comprise a probe that binds with a target compound (para. 0024, 0081), and further teach detection of a binding event with the membrane bound protein. Lahiri et al. further teach detection of a binding event using the probe array after incubation in a humid chamber at room temperature for a hour (para. 0094), which would also enable lateral distribution of the lipid molecules. Although Lahiri et al. do not specify the incubation would be to enable lateral fluidity of the lipids, applicants have not specified any other requirement to enable lateral fluidity of the lipids other than to incubate the array in a humid chamber, this limitation would read on the method of Lahiri et al. since Lahiri et al. also teach the step of incubating the array in a humid chamber. Lahiri et al., however, do not specify monitoring for binding activity of at least one of the biological lipid membranes with an unknown toxin in a sample by comparing the binding pattern of the unknown toxin with that of a known toxin to identify and detect the presence of the toxin in the sample.

Löfås, however, teaches liposomes containing ganglioside G<sub>M1</sub> for detecting cholera toxins in a sample (column 5, 6, example 1), wherein cholera is a bacterial toxin, as evidenced by Hildreth (see para. 0041). Löfås further teaches that this allows for the detection and

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determination of the specific activity of the lipid bilayer for binding to cholera toxins, thus providing important information of binding of cholera toxin with biological membranes (column 6, lines 1-28).

Cass further teaches comparing an array binding pattern with the array binding pattern of known test ligands in order to allow accurate identification of a test compound (para. 0042-0045, 0060).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have compared the binding pattern of an unknown toxin in a sample with that of known toxins, as suggested by Cass et al., in order to allow for accurate identification of a test compound.

28. With respect to claim 50, Lahiri et al. teach synthetic or natural analytes (para. 0068), as discussed above.

29. With respect to claims 55, as discussed above, the amines used by Lahiri et al. may be  $\gamma$ -aminopropylsilane (para. 0010).

30. With respect to claims 56, as discussed above, the amines used by Lahiri et al. may be polyethyleneimine (para. 0054).

### ***Response to Arguments***

31. Applicant's arguments with respect to claims 1, 4-5, 10-18, 42-62, 64, 66 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

32. No claims are allowed.

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33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/  
Primary Examiner, Art Unit 1641